K073061

Summary of Safety and Effectiveness

FEB 29 2008

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter:

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Name of the Device: The Proxivent Kit

Predicate Devices:

The Proxivent kit is substantially equivalent to both Duraflor® dental cavity varnish manufactured by Pharmascience Inc. Canada, subject of K931096, and Duraphat® dental cavity varnish, subject of K931096, manufactured initially by Inpharma and Woelm Pharma in Germany and now manufactured by Colgate Oral Pharmaceuticals Inc.

Description of the Device:

The Proxivent Kit is a fluoride containing varnish system intended for use as a desensitizing agent on the surface area of hypersensitive or potentially sensitive teeth where dentin or cementum is directly or indirectly exposed. The Proxivent Kit comprises two components, Proxivent Varnish and Proxivent Matrix Pads. The varnish component is intended for application on easily accessible sites such as the buccal and lingual surfaces. The matrix pads include three shapes; round discs; an anatomically H-shaped conformation and an elongated H-shaped conformation (HL). The pads are made of varnishes containing cross-linked gelatin that obdurate dental tubules and release fluoride to strategically targeted tooth surfaces for optimal effects at the microscopic and molecular level at sites not easily accessed. Proxivent matrix pads are small, comfortable devices that dental professionals can position, for example, between the teeth or at a furcation where there is, or could be, sensitivity. Proxivent matrix pads are engineered to expand gently and lock into place, soften and protect exposed dentin and exude non-toxic micro-doses of fluoride onto and into the tooth crystals (e.g., of the cemetum and dentin) at inaccessible regions, for example, furcations and between the teeth. The matrix pads biodegrade following their fluoride release.

Ahron Jodaikin, BDS, MSc, PhD,
Chief Scientist

Oct. 24, 2007
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 29 2008

Coll Partners Limited
C/O Dr. Eli M. Orbach
General Manager
International Regulatory Consultants
POB 6718
Efrat,
ISRAEL 90435

Re: K073061
Trade/Device Name: Proxivent Kit
Regulation Number: 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: January 23, 2008
Received: January 23, 2008

Dear Dr. Orbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

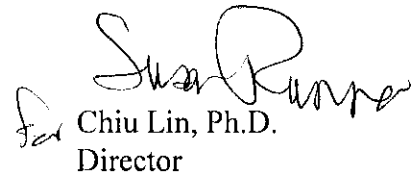
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use (separate page):

510(k) Number (if known): K073061

Device Name: Proxivent Kit

Indications For Use:

The Proxivent Kit is a fluoride containing varnish system intended for use as a desensitizing agent on the surface areas of hypersensitive or potentially sensitive teeth where dentin or cementum is directly or indirectly exposed.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Page 1 of ____

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073061